



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March, 18, 2020

Maureen Purcell
EPA Registrations Manager
Claire Manufacturing Company
1000 Integram Drive
Pacific, MO 63069

Subject: Label Amendment – Adding the Emerging Viral Pathogens Claim
Product Name: Claire Disinfectant Spray Q
EPA Registration Number: 706-111
Application Date: 03/06/2020
Decision Number: 560781

Dear Ms. Purcell:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

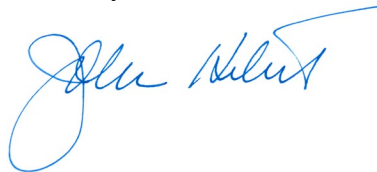
2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup are large non-enveloped, and enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Adenovirus Type 2, Rotavirus, Rhinovirus type 37 and Poliovirus type 1 is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact Aline Heffernan at 703-347-8602 or via email at Heffernan.Aline@epa.gov.

Sincerely,



John Hebert, Chief
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Stamped Label

[] Denotes optional language
 ([]) Denotes one of the options within the brackets must be chosen
 { } Denotes language that does not appear on the market label
 () Denotes language that is intended to be included on the label with parenthesis
 The phrase 'This product' may be replaced with the product name or left off.

Claire Disinfectant Spray Q

Spray Disinfectant

For Use on Hard, Non-porous Environmental Surfaces and Soft Spot Surface Sanitizer applications.

{Insert optional marketing claims from list below.}

Active Ingredients:

Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₈ , 5% C ₁₂)	
dimethyl benzyl ammonium chloride	0.16%
Alkyl (68% C ₁₂ , 32% C ₁₄)	
dimethyl ethylbenzyl ammonium chloride	0.16%
Other Ingredients	99.68%
Total	100.00%

Keep Out of Reach of Children

CAUTION

See [back][side] panel for First Aid and additional Precautionary Statements.

EPA Reg. No. 706-111

EPA Est. XXX

Refer to bottom of container for production facility

{Optional Marketing Claims:}

Antibacterial

Bactericidal

*Virucidal

Fungicidal

Tuberculocidal

Germicidal

Country Fresh Scent

Country Garden Scent

Lavender Scent

Lemon Scent

Disinfect[s]

Deodorize[s] [Deodorizer]

Sanitize[s]

Sanitizes soft non-food contact surfaces as a spot treatment.

Kills Common Kitchen Germs

Kills Pandemic 2009 H1N1 Influenza A *virus [formerly called "swine flu"]

Kills 99.9% Germs

Kills 99.9% *viruses and bacteria

Kills flu viruses

Kills (TB) Mycobacterium bovis

Multipurpose Disinfectant

Controls Mold and Mildew

ACCEPTED

03/18/2020

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 706-111

[] Denotes optional language
([]) Denotes one of the options within the brackets must be chosen
{ } Denotes language that does not appear on the market label
() Denotes language that is intended to be included on the label with parenthesis
The phrase 'This product' may be replaced with the product name or left off.

Controls mold and mildew on [mattresses], [shower curtains], [painted or finished walls], [attics and damp, musty areas].

Eliminates Odors

Multipurpose

Ready-to-use

No mixing

This [product] is effective as a [sanitizer][disinfectant] on hard, non-porous, non-food contact surfaces in: {Insert use sites from list below.}

Ambulances

Homes

Residential Dwellings

Hospitals

Healthcare

Nursing Homes

Clinics

Medical Facilities

Businesses

Hotels

Motels

Restaurants

Schools

Institutions

Housekeeping [and in-home use]

Kitchens

Bathrooms

Commercial Establishments

This [product] is for use as a [sanitizer][disinfectant] on hard, non-porous non-food contact surfaces such as: {Insert surfaces from list below.}

Doorknobs

Light switches

Toilet[s] [seats]

[Kills germs on] high-touch surfaces [such as] [{see list of surfaces}].

Sinks

Kitchen appliance surfaces

[For] Bowling shoes, skates, ski and snowboard boots

Bathtubs

Showers

Garbage cans

This [product] is effective as a disinfectant [on] food contact surfaces [in]: {Insert use sites from list below.}

Homes

Restaurants

Kitchens

[And other] commercial establishments

[] Denotes optional language
([]) Denotes one of the options within the brackets must be chosen
{ } Denotes language that does not appear on the market label
() Denotes language that is intended to be included on the label with parenthesis
The phrase 'This product' may be replaced with the product name or left off.

This [product] is for use as a disinfectant on food contact surfaces [such as]: {Insert surfaces from list below.}

Toys
Countertops
Tables
Appliances

{Note to Reviewer: ATCC etc. references are optional on the label.}

[This product] kills the following bacteria, fungi and *viruses in 3 minutes on pre-cleaned hard, non-porous surfaces:

{Select claims as desired for 3 minute contact time.}

Pseudomonas aeruginosa (ATCC 15442)
Salmonella enterica (ATCC 10708)
Staphylococcus aureus (ATCC 6538)
Acinetobacter baumannii Multi Drug Resistant (ATCC 19606)
Carbapenem Resistant *Escherichia coli* (CDC 81371)
Carbapenem Resistant *Klebsiella pneumoniae* (ATCC BAA-1705)
Enterobacter aerogenes (ATCC 13048)
Enterococcus faecium (ATCC 51559)
Escherichia coli (ATCC 11229)
Klebsiella pneumoniae (ATCC 4352)
Listeria monocytogenes (ATCC 19117)
Staphylococcus aureus- MRSA (ATCC 33592)
Staphylococcus aureus- CA-MRSA Genotype USA 300 (NARSA NRS 384)
Staphylococcus aureus- CA-MRSA Genotype USA 400 (NARSA NRS 123)
Shigella dysenteriae (ATCC 11835)
Streptococcus pyogenes (ATCC 19615)
Staphylococcus aureus –VISA (CDC HIP 5836)
Enterococcus faecalis –VRE (ATCC 51575)
Campylobacter jejuni (ATCC 29428)
Candida albicans (ATCC 10231)

*Viruses:

Adenovirus Type 2*
2009-H1N1 Influenza A virus*
Influenza B virus*
Human Immunodeficiency virus type 1 (HIV-1)*
Herpes simplex virus type 1*
Herpes simplex virus type 2*
Rotavirus*
Vaccinia virus*
Rhinovirus type 37*

[] Denotes optional language
 ([]) Denotes one of the options within the brackets must be chosen
 {} Denotes language that does not appear on the market label
 () Denotes language that is intended to be included on the label with parenthesis
 The phrase 'This product' may be replaced with the product name or left off.

[This product] kills (TB) *Mycobacterium bovis* (ATCC 35743) in 10 minutes at 22.5°C on pre-cleaned hard, non-porous surfaces.

[This product] kills Poliovirus type 1* in 5 minutes on pre-cleaned hard, non-porous surfaces.

[This product] sanitizes and kills 99.9% of *Staphylococcus aureus* (staph) and *Enterobacter aerogenes* in 3 minutes on pre-cleaned, hard, non-porous surfaces.

Fungus:

{State fungicidal claims as 10 minute contact time}

Trichophyton interdigitale (Athlete's Foot Fungus) (ATCC 9533)

{Select claims as desired for Mildew-Fungistatic use.}

Aspergillus niger (ATCC 6275)

<< EMERGING VIRAL PATHOGENS CLAIMS – Hard, non-porous surface >>

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

-Enveloped Viruses

-Large Non-Enveloped Viruses

<i>For an emerging viral pathogen that is a/an...</i>	<i>...following the directions for use for the following organisms on the label:</i>
Enveloped virus	<u>One of the following:</u> Poliovirus type 1, ATCC VR-1562, Strain Chat
Large, non-enveloped virus	<u>One of the following:</u> Poliovirus type 1, ATCC VR-1562, Strain Chat

[Product name] has demonstrated effectiveness against viruses similar to ***[name of emerging virus]*** on hard, ***[porous and/or non-porous surfaces]***. Therefore, ***[product name]*** can be used against ***[name of emerging virus]*** when used in accordance with the directions for use against ***[name of supporting virus(es)]*** on ***[hard, porous/non-porous surfaces]***. Refer to the ***[CDC or OIE]*** website at ***[pathogen-specific website address]*** for additional information.

[Name of illness/outbreak] is caused by ***[name of emerging virus]***. ***[Product name]*** kills similar viruses and therefore can be used against ***[name of emerging virus]*** when used in accordance with the directions for use against ***[name of supporting virus(es)]*** on ***[hard, porous/non-porous surfaces]***. Refer to the ***[CDC or OIE]*** website at ***[website address]*** for additional information.”

[] Denotes optional language
([]) Denotes one of the options within the brackets must be chosen
{ } Denotes language that does not appear on the market label
() Denotes language that is intended to be included on the label with parenthesis
The phrase 'This product' may be replaced with the product name or left off.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Shake Well Before Each Use. Point valve opening toward area to be cleaned, press down firmly and spray evenly.

To Disinfect: After hard, non-porous surface is cleaned, hold can upright 6" to 8" from area to be treated. Spray until surface is thoroughly wet. Allow to dry without wiping or allow spray to contact treated surface for a minimum of 3 minutes prior to wiping. Reapplication is necessary if surface is dried before contact time is achieved. When used on toys or food contact surfaces such as countertops, tables and appliances, thoroughly rinse surfaces with potable water before use. Do not use on utensils, dishes or glasses.

To Sanitize Non-Food Contact Surfaces: After hard, non-porous surface is cleaned, hold can upright 6" to 8" from area to be treated. Spray until surface is thoroughly wet. Allow to dry without wiping or allow spray to contact treated surface for a minimum of 3 minutes prior to wiping. Reapplication is necessary if surface is dried before contact time is achieved.

To Kill (TB) Mycobacterium bovis: Pre-clean surfaces, hold can upright 6" to 8" from area to be treated. Spray until surface is thoroughly wet. Allow to dry without wiping or allow spray to contact treated surface for a minimum of 10 minutes prior to wiping. Reapplication is necessary if surface is dried before contact time is achieved. When used on toys or food contact surfaces such as countertops, tables and appliances, thoroughly rinse surfaces with potable water before use. Do not use on utensils, dishes or glasses.

To Kill Poliovirus Type 1: After surface is cleaned, hold can upright 6" to 8" from area to be treated. Spray until surface is thoroughly wet. Allow to dry without wiping or allow spray to contact treated surface for a minimum of 5 minutes prior to wiping. Reapplication is necessary if surface is dried before contact time is achieved. When used on toys or food contact surfaces such as countertops, tables and appliances, thoroughly rinse surfaces with potable water before use. Do not use on utensils, dishes or glasses.

For use as a fungicide [against Trichophyton interdigitale (Athlete's Foot)]: Apply to clean surface holding can upright 6" to 8" from area to be treated. Spray until surface is thoroughly wet. Allow to dry without wiping or allow spray to contact treated surface for a minimum of ten minutes prior to wiping. Reapplication is necessary if surface is dried before contact time is achieved.

For Spot Sanitization of Soft Non-food Contact Surfaces: After surface is cleaned, hold can upright 6" to 8" from area to be treated. Spray until surface is thoroughly wet. Allow to dry without wiping or allow spray to contact treated surface for a minimum of three minutes prior to wiping. Reapplication is necessary if surface is dried before contact time is achieved.

For Control of Mold and Mildew: Apply by holding can upright 6" to 8" from surface to be treated. Spray until surface is completely wet. Let air dry. Repeat application at weekly intervals or when mildew growth reappears.

***Kills HIV on Pre-Cleaned Environmental Surfaces Previously Soiled with Blood/Body Fluids** in health care settings or other settings in which there is an expected likelihood of soiling

[] Denotes optional language
 ([]) Denotes one of the options within the brackets must be chosen
 { } Denotes language that does not appear on the market label
 () Denotes language that is intended to be included on the label with parenthesis
 The phrase 'This product' may be replaced with the product name or left off.

of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus* Type 1 (HIV) (associated with AIDS): **Special Instructions for Cleaning and Decontamination Against HIV on Surfaces/Objects Soiled with Blood/Body Fluids:**
Personal Protection: When handling items soiled with blood or body fluids, use barrier protection: disposable latex gloves, gowns, masks and eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant. **Contact Time:** Spray surface to be treated 3-4 seconds, from a distance of 6-8 inches, until surface is wet. Allow spray to dry without wiping or allow spray to contact treated surface for a minimum of three minutes except for Poliovirus Type 1 which requires five minutes, prior to wiping. **Disposal of Infectious Materials:** Autoclave blood and other body fluids and disposed of according to federal, state and local regulations for infectious waste disposal.

This product is not for use on medical devices or medical equipment surfaces.

Storage and Disposal

Product Storage: Store in a cool, dry (preferably locked) place inaccessible to children and pets and away from direct sunlight, windows, flames and other sources of heat or ignition. **Product Disposal:** Wastes resulting from the use of this product may be disposed on site or at an approved waste disposal facility. **Container Disposal:** Non-refillable container. Do not refill or reuse this container. Do not puncture or incinerate! **If empty:** Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions.

{Batch Code/Lot Number will appear either on the label or the container per PR Notice 2007-4.}

PRECAUTIONARY STATEMENTS

Hazards to Humans & Domestic Animals

CAUTION: Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

First Aid

If in Eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes.
If on Skin	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes.
Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-866-836-8855 {or other appropriate number} for emergency medical treatment information.	

{Note: The grid format for the First Aid statements will be used if market label space permits; otherwise a paragraph format will be used.}

[] Denotes optional language
 ([]) Denotes one of the options within the brackets must be chosen
 { } Denotes language that does not appear on the market label
 () Denotes language that is intended to be included on the label with parenthesis
 The phrase 'This product' may be replaced with the product name or left off.

Physical or Chemical Hazards

Flammable. Contents under pressure. Do not use or store near fire, sparks or heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. Incineration of container may cause explosion.



[Point spray pattern toward dot {or similar instructional text}]
 Aerosol Spray



[Contains no CFCs or other ozone depleting substances.]
 [Federal regulations prohibit CFC propellants in aerosols.]



{Package display}

[Made in the USA with domestic and foreign components.]



Nonfood Compounds
 (Category Code)

{Note: The (Category Code) will contain the specific registration number for the product.}

[] Denotes optional language
([]) Denotes one of the options within the brackets must be chosen
{ } Denotes language that does not appear on the market label
() Denotes language that is intended to be included on the label with parenthesis
The phrase 'This product' may be replaced with the product name or left off.

A Product of



Claire Manufacturing Company

1000 Integram Drive

Pacific, MO 63069

[www.clairemfg.com]

{Alternate Brand Names}

Claire Disinfectant Spray Lemon Scent

Claire Disinfectant Spray Country Fresh Scent

Claire Disinfectant Spray Floral Scent

Claire Disinfectant Spray Lavender Scent

{End of Alternate Brand Names}